PRESS RELEASE

Ombudsman probes Government's mechanism for monitoring vaccines provided by private healthcare facilities

The Ombudsman, Ms Winnie Chiu, today (20 August) announced a direct investigation into the Government's current mechanism for monitoring the vaccines provided by private healthcare facilities in Hong Kong, with a view to identifying any room for improvement.

During joint operations conducted in July 2019, the Department of Health (DH) and the Customs and Excise Department (C&ED) uncovered suspected counterfeit nine-valent human papillomavirus (HPV) vaccines provided by medical centres. Results of analysis revealed that samples of the seized products contained no active ingredients of an HPV vaccine, but only sodium and chloride, which are commonly found in saline solution. It was also found that the samples might have been contaminated by microbes and could pose a risk to those who were administered the products. At the same time, the Office of The Ombudsman had received complaints about parallel imported or counterfeit nine-valent HPV vaccines and taken note of wide media coverage of the incident.

As pharmaceutical products defined under the Pharmacy and Poisons Ordinance (PPO), all vaccines must satisfy the criteria of safety and quality prescribed by the Pharmacy and Poisons Regulations. Registration with the Pharmacy and Poisons Board of Hong Kong is required for the sale or distribution of vaccines in the territory. The Board has also formulated the Code of Practice for Holder of Wholesale Dealer Licence under the PPO for compliance by licensed wholesale dealers in procuring, importing or selling vaccines. The import and export of vaccines is regulated by the Import and Export Ordinance (IEO), under which wholesale dealers are required to apply for an import licence from the DH for each importation. At present, the DH's Drug Office and the C&ED are responsible for taking enforcement action under the PPO and IEO respectively.

The Office's preliminary inquiry revealed that the local

emergence of parallel imported/counterfeit products in 2019 was mainly due to the fact that the demand for nine-valent HPV vaccine far exceeded the limited supply, prompting unscrupulous dealers to provide private healthcare facilities with parallel imported or counterfeit products. Upon realising the situation, the authorities took follow-up action under the established mechanism and stepped up monitoring measures. This direct investigation aims at evaluating whether the current monitoring mechanism is effective and identifying any room for improvement. The Office's investigation covers the Food and Health Bureau, the DH and the C&ED.

Ms Chiu said, "Vaccines are pharmaceutical products administered directly into the human body, so it is essential to ensure their quality and safety. To prevent substandard or even counterfeit vaccine products from circulating in the market and posing a threat to public health, the Government must properly play the role of gatekeeper. Through this direct investigation, I hope to explore ways for further improving the current monitoring mechanism and enhance public awareness of the Government's monitoring efforts."

The Ombudsman is inviting views from members of the public on this topic. Written submissions should reach the Office by 21 September 2020:

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Office of The Ombudsman
20 August 2020

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